IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CLOYS HAYNES and DARLENE HAYNES	)	
Plaintiffs,	)	CIVIL ACTION FILE
v.	)	NO.: 1:09-cv-2700
CYBERONICS, INC.	)	(Removed from the State Court of Gwinnett County, Georgia
Defendant.	)	Civil Action File No. 09C-

AFFIDAVIT OF PHILLIP R. KENNEDY, M.D.

PERSONALLY APPEARED before the undersigned officer duly authorized by law to administer oaths came Phillip R. Kennedy, M.D. and, who, after being duly sworn and deposed, states as follows:

1.

My name is Phillip R. Kennedy. I am over the age of 18 and competent to give this Affidavit in support of Plaintiffs' Brief In Opposition to Defendant Cyberonics' Motion For Summary Judgment. I am familiar with the above captioned matter as the Plaintiff's treating neurologist and make this Affidavit based upon my personal knowledge of events I have observed and information contained in Plaintiff's medical records.

2.

I am a physician practicing continuously in the field of neurology since the year 1994. My practice is located at 3400 McClure Bridge Road, Suite 401, Duluth, Georgia 30096.

3.

In my practice, I treat and evaluate patients with Vagal Nerve Stimulator systems and am familiar with how the system works and the expected results. Specifically, I have treated such patients who have received VNS stimulators manufactured by Cyberonics. Cyberonics sales representatives frequently visit my office with information on their product.

4.

In addition, I have received the following training from Cyberonics with respect to monitoring the VNS device and adjusting the voltage levels:

a. Cyberonics representative in 2003

b. Further advice from time to time

5.

Plaintiff Cloys Haynes was referred to me by Dr. Karisney back in July 2004 for evaluation of recent increase in frequency of seizures. Plaintiff's seizures began after he sustained a severe head injury in a motor vehicle accident on or about April 2001.

6.

I tried several medication regimens to try to control Plaintiff's seizures but over time, Plaintiff's seizures were not responding to the medications.

7.

On or about April 2007, I recommended that Plaintiff consider Vagal Nerve Stimulation Therapy. I gave Plaintiff and his wife the contact information for a representative of Cyberonics and instructed them to call the representative for more information on the VNS device and how it could benefit Plaintiff, as well as the specifics involved in implantation.

8.

I also explained the risks and benefits of the VNS device as I understood them to be based upon the information that I had received from Cyberonics sales representatives and in my experience in working with the VNS devices with other patients.

9.

The Plaintiff notified me that he wanted to go forward with implantation of the VNS device and I referred Plaintiff to Dr. Zarge for surgical implantation of a VNS device.

10.

Plaintiff had a VNS device implanted on July 17th, 2007 by Dr. Zarge. The VNS device was manufactured by Cyberonics.

11.

After implantation of the VNS device, Plaintiff made several follow up visits to my office so that I could adjust the voltage of the VNS device in accordance with the manufacturer's instructions to achieve the optimal therapeutic voltage for Plaintiff. Over the course of several visits, I gradually increased the voltage as instructed by Cyberonics.

12.

On or about September 19th, 2007 Plaintiff made a visit to my office at which time he reported that he was still having seizures. He also reported a tingling sensation in his shoulder when his arm was down. I increased his voltage again since he was still experiencing seizures, pursuant to the manufacturer's instructions.

13.

The next day on September 20th, 2007, Plaintiff came back to my office and informed me that he had been to the Emergency Room the evening before with symptoms that he believed were related to a heart attack. While at the hospital, he experienced a very sudden and severe shock that he believed to be caused by the VNS device. His VNS device was disabled at the hospital upon advice of the ER

staff. I ordered an MRI to rule out the possibility that Plaintiff had experienced a stroke. The MRI results ruled out the possibility of a stroke and showed no change in Plaintiff's brain over prior MRIs.

14.

Since there were no other apparent causes of Plaintiff's sudden symptoms, I concluded that the cause was a malfunction of the VNS device. The VNS device was turned off in my office on September 20th, 2007 and I recommended at that time that Plaintiff have the device removed and replaced.

15.

Plaintiff underwent surgical removal and replacement of the VNS device on November 30th, 2007 by Dr. Zarge and again reported to my office for follow up to adjust the voltage of the VNS device.

16.

Plaintiff did not report any similar symptoms as he experienced on September 19th, 2007 after the 1st VNS device was turned off or with the use of the 2nd VNS device.

17.

[redacted] It is my opinion that the first VNS device implanted on July 17th, 2007 malfunctioned, causing the Plaintiff to be electrically shocked.

18.

The VNS device is not supposed to shock the patient in the way that it shocked the Plaintiff and this was not listed as an adverse event in the product information that I was given by Cyberonics.

Further Affiant Sayeth Not.

Philip R. Kennedy, M.D.

Sworn to and subscribed before
me this 28th day of January, 2011.

Jennifer Skipper
Notary Public
my commission expires 1/19/2013